DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 30, 2014

Arthro-DIF
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K141695
Trade/Device Name: Acrosspine Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: November 28, 2014
Received: December 1, 2014

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141695

Device Name

Acrosspine Pedicle Screw System

Indications for Use *(Describe)*

The Acrosspine Pedicle Screw System is intended for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K141695

Date Prepared: November 28, 2014

Submitter Contact: Jean-Charles Roussouly
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Regulatory Contact: Rich Jansen, Pharm. D.
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Trade Name: Acrosspine Pedicle Screw System
Product Class: Class III
Classification: 888.3070 Pedicle Screw Spinal System
Common Name: Pedicle Screw System
Product Codes: NKB, MNI, MNH
Panel Code: 87

Indications for Use:
The Acrosspine Pedicle Screw System is intended for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Device Descriptions:
The Arthro-DIF Acrosspine Pedicle Screw System is an implant device made from an unalloyed titanium and 6Al4V Titanium Alloy. It is to be implanted from the posterior approach. The screws are available in 5.5, 6.5 and 7.5mm diameters and in lengths from 35-60 mm. The screws are available as polyaxial screws. All rods are available in 5.5mm diameter with curved rod in lengths from 40-100 mm, and straight rods from 150-300mm.

Predicate Device(s):
The Arthro-DIF Acrosspine Pedicle Screw System is substantially equivalent to the Expedium System by DePuy Spine (K073126), the S4 System by Aesculap (K090657), the

Easyspine system by LDR Spine (K082592) and the AnyPlus Spinal System by GS Medical (K091717 - Primary Predicate).

Performance Standards:
Pre-clinical testing was performed on the Arthro-Dif Acrosspine Pedicle Screw System. Testing included:

Test	ASTM Standard
Static Compression Bend	F1717-13
Dynamic Compression Bend	F1717-13
Static Torsion	F1717-13
Axial Pullout	F543-13
Torque to Failure	F543-13
Axial Slip	F1798-97 (08)
Flexural Grip	F1798-97 (08)
Torsional Grip	F1798-97 (08)

Conclusion:
Arthro-DIF concludes that the Arthro-DIF Acrosspine Pedicle Screw System is substantially equivalent to the predicates in regard to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.